UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION

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CONCORDIA PHARMACEUTICALS INC., S.À.R.L.

Plaintiff,

v.

WINDER LABORATORIES, LLC AND STEVEN PRESSMAN

Defendants.

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Civil Action No. 2:16-cv-00004-WCO

COMPLAINT

Plaintiff Concordia Pharmaceuticals Inc., S.à.r.l. ("Plaintiff" or "Concordia"), by and through their undersigned counsel, for their Complaint against Defendant Winder Laboratories, LLC ("Defendant Winder") and Defendant Steven Pressman ("Defendant Pressman" and, collectively, "Winder" or the "Defendants"), hereby allege and state the following:

NATURE AND BASIS OF ACTION

1. This action arises out of Defendants' knowing and willful false and misleading advertising and promotion of the pharmaceutical product, B-DONNA. Defendants' actions constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); trademark infringement under Section 32 of the Lanham Act; federal unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 15 U.S.C. § 1114; violation of the Georgia Uniform Deceptive Practices Act, O.C.G.A. § 10-1-372; tortious interference in violation of Georgia common law; and unjust enrichment in violation of Georgia common law.

2. Plaintiff seeks temporary, preliminary and permanent injunctive relief; actual damages; punitive damages; and recovery of Plaintiff's costs and reasonable attorneys' fees incurred in connection with this action. Plaintiff also seeks cancellation of Defendants' U.S. Reg. No. 4,883,086 pursuant to 15 U.S.C. § 1119.

THE PARTIES

3. Plaintiff is a *société à responsabilité limitée* incorporated and existing under the laws of the Grand Duchy of Luxembourg, having its registered office at 8-10, avenue de la Gare, L-1610 Luxembourg and registered with the *Registre de*

Commerce et des Sociétés, *Luxembourg* under number B 200344, and having a Barbados branch office located at 5 Canewood Business Centre, St. Michaels, Barbados, BB11005.

4. Upon information and belief, Defendant Winder is a Georgia limited liability company with its principal office at 716 Patrick Industrial Lane, Winder, Georgia 30680, and the manufacturer and seller of the B-DONNA products. Defendant Winder may be served through its Registered Agent, Incorp Services Inc., at 2000 Riveredge Pkwy NW St. 885, Atlanta, Georgia 30328.

5. Upon information and belief, Defendant Pressman resides at 1303 Wellesley Ave., Los Angeles, California 90025-2058, and is the managing member of Defendant Winder.

JURISDICTION

6. This Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338. The Court also has supplemental jurisdiction over Plaintiff's state and common law claims pursuant to 28 U.S.C. § 1367.

7. Venue is proper in this district pursuant to 28 U.S.C. § 1391. A substantial part of the events giving rise to the claims against Defendants occurred in this District.

8. This Court has personal jurisdiction over Defendants because Winder is a Georgia limited liability company and Defendants regularly transact business in the State of Georgia. Moreover, the Defendants have listed their products for sale in online databases that are used by purchasers of PBA pharmaceuticals in this District, and, accordingly, Defendants have purposefully directed their business activities toward this District. In addition, the Defendants have caused harm to Plaintiff in this District. Through such conduct, Defendants have purposefully availed themselves of the privileges of conducting business in this District, and, when engaging in such conduct, it was reasonably foreseeable that Defendants would be subjected to this Court's jurisdiction.

BACKGROUND FACTS

9. For nearly 80 years, the DONNATAL® brand of pharmaceutical products has helped improve the lives of individuals suffering from irritable bowel syndrome (IBS), a condition characterized by abdominal pain, bloating, and irregular diarrhea or constipation.

10. The DONNATAL pharmaceutical products are a proprietary combination medicine used as adjunctive therapy in the treatment of IBS, as well

as acute enterocolitis. Because DONNATAL products must be used under the supervision of a healthcare provider, they are available by prescription only.

11. DONNATAL products are marketed and distributed by Plaintiff in two unique formulations: (1) immediate release DONNATAL Tablets and (2) fast-acting DONNATAL Elixir, available in either grape or mint flavor (collectively, "DONNATAL").

12. The active formulation of DONNATAL products comprises a combination of phenobarbital and belladonna alkaloids ("PBA").

13. DONNATAL is labeled as containing the following active ingredients in the following strengths: (1) phenobarbital, 16.2 mg; (2) hyoscyamine sulfate, 1037 mg; (3) atropine sulfate, .0194 mg; and (4) scopolamine hydrobromide.

14. In 1962, when Congress amended the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the Food and Drug Administration (FDA) was required to conduct a retrospective evaluation of drugs that had previously been approved under the FD&C Act between its enactment in 1938 and 1962. DONNATAL was one of more than 3,400 drugs affected by this amendment. 21 U.SC. § 301 *et seq.*

15. In the 1970s, the FDA began a process of evaluating the safety and efficacy of PBA drug products under the Drug Efficacy Study Implementation ("DESI") review program. On June 20, 1978, the FDA required any drugs that were involved in the review process to obtain an approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") to remain on the market. 43 Fed. Reg. 26,490 (June 20, 1978).

16. On December 30, 1980, Plaintiff's predecessor, A.H. Robins Company ("Robins"), obtained conditionally approval ANDAs for its DONNATAL Tablets (ANDA 88-676) and DONNATAL Elixir (ANDA 86-661).

17. Conditionally approved ANDAs have the same status as safety-only NDAs that were approved prior to the 1962 amendments. Drug products manufactured under such a conditionally approved ANDA can be legally marketed until the FDA resolves questions about their effectiveness under the FD&C Act.

18. On May 6, 1983, the FDA published in the Federal Register a notice of an opportunity for a hearing ("NOOH") regarding the regulatory status of PBA drug products, including DONNATAL. Under the FD&C Act, the FDA requires the holders of approved NDAs or those alleging such approvals to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of

fact exist about the effectiveness of the drug that require an administrative hearing for resolution.

19. Under the NOOH process, only those companies that actively participated in this hearing process were permitted to legally market their PBA drug products. Plaintiff's DONNATAL products have been under this NOOH since 1983, and thus have been allowed to continue to remain on the market pending final resolution of the hearing process. The hearing process for PBA products has not yet been completed.

20. Upon information and belief, Plaintiff is the only company that continues to participate in the FDA DESI review process for PBA products.

21. In September 2011, the FDA established a Compliance Policy Guide confirming that any drug product coming to market for the first time after September 19, 2011 alleging any legal status under the DESI review was illegal and subject to immediate legal action by the FDA.

22. Accordingly, upon information and belief, Plaintiff is the only company that is legally permitted to market PBA products.

23. Plaintiff maintains contractual relationships with pharmaceutical manufacturers, distributors and/or suppliers in order to make and sell

DONNATAL. These contractual relationships result in economic benefits to Plaintiff, and will continue to do so in the future. These contractual relationships are standard for the industry.

THE DONNATAL MARK

24. The DONNATAL mark is a coined or fanciful mark that is inherently distinctive.

25. Plaintiff and its predecessors-in-interest have continuously used the DONNATAL trademark as the brand name for its line of IBS pharmaceutical products throughout the United States since at least as early as April 1, 1936.

26. All right, title and interest in the DONNATAL mark were assigned to Plaintiff on or around May 15, 2014.

27. Plaintiff and its predecessors-in-interest have engaged in extensive advertising and promotion of the DONNATAL mark to gain goodwill and public recognition of its products. Plaintiff has expended substantial sums of money and resources to advertise and market DONNATAL to wholesalers, distributors, pharmacists, medical professionals, and the consuming public.

28. Plaintiff enjoys a strong reputation and a high level of goodwill among relevant consumers throughout the United States in connection with the products sold under the DONNATAL mark.

29. As a result of Plaintiff's marketing efforts and its long and substantially exclusive use of the mark, the trade and the consuming public identify the DONNATAL mark and the products offered thereunder solely with Plaintiff in this jurisdiction and throughout the United States.

30. The DONNATAL mark was registered by the United States Trademark and Patent Office ("USPTO") as U.S. Reg. No. 338,733 (the "DONNATAL Registration") in connection with "medicinal preparation used in the treatment of gastro-intestinal disturbances" in International Class 5 by Robins on September 15, 1936. A copy of the Certificate of Registration is attached hereto as Exhibit A.

31. The DONNATAL Registration is valid and subsisting, and in full force and effect.

32. All rights in the DONNATAL Registration were assigned to Plaintiff on or around May 15, 2014, the assignment of which has been duly recorded with the USPTO.

33. As such, Plaintiff is the is the sole owner of the federally-registered and common law trademark rights in the DONNATAL mark for use in connection with pharmaceutical preparations for the treatment of gastro-intestinal diseases.

DEFENDANTS' UNLAWFUL CONDUCT

34. Upon information and belief, Defendant Winder is a Georgia-based contract manufacturer of "generic" drug products.

35. Upon information and belief, Defendant Winder is owned and controlled by Defendant Pressman.

36. Plaintiff is in no way affiliated with Defendants or their related entities.

37. Upon information and belief, Defendants are seeking to exploit the reputation and success of DONNATAL by marketing and selling an unauthorized "generic" version of DONNATAL tablets under the confusingly similar B-DONNA name.

38. Upon information and belief, Defendants first began planning to manufacture a generic version of DONNATAL in 2013. At that time, the knock-off DONNATAL product was going to be developed and manufactured by

Defendants and marketed by another party, Method Pharmaceuticals, LLC ("Method") under the name "Me-PB-Hyos."

39. Following the listing of the Me-PB-Hyos product with Medi-Span and other drug databases, Plaintiff sued Defendants and Method in the Western District of Virginia in *Concordia Pharmaceuticals, Inc. v. Method Pharmaceuticals, LLC et al,* Docket No. 3:14-cv-00016.

40. On March 6, 2015, in an attempt to be dismissed from the litigation, Defendants represented to the Court that they were not manufacturing Me-PB-Hyos or any other DONNATAL equivalent for Method and that they had not participated in the copying of DONNATAL labels.

41. Defendants were subsequently dismissed from that action for lack of jurisdiction on July 1, 2015.

42. Upon information and belief, at the same time they were making these representations to Plaintiff and the Court, Defendants were actively taking steps to manufacture and sell a generic version of DONNATAL.

43. On February 27, 2015, Defendants filed an intent-to-use federal trademark application, Application Serial No. 86/549,114 (the "Application"), to

register the mark B-DONNA in connection with "Pharmaceutical preparations and substances for the treatment of gastro-intestinal diseases" in International Class 5.

44. On October 15, 2015, Defendants filed a Statement of Use with the USPTO in connection with the Application, claiming first use of the B-DONNA mark anywhere on February 14, 2015 and first use in commerce on March 10, 2015.

45. On January 5, 2016, the Application matured into registration under U.S. Reg. No. 4,883,086. A copy of the Certificate of Registration for the B-DONNA mark is attached hereto as Exhibit B.

46. Upon information and belief, although Defendant Pressman swore to the USPTO that Defendant Winder had been using the B-DONNA mark in commerce since at least as early as March 10, 2015, Defendants did not obtain a National Drug Code ("NDC") number for any B-DONNA product until December 2015.

47. On or around December 2015, Defendants obtained National Drug Code ("NDC") numbers for both 100 count and 1000 count bottles of B-DONNA oral tablets.

48. Upon information and belief, after obtaining the NDC codes, Defendants listed the B-DONNA pharmaceutical products with FDA and subscription pharmaceutical drug databases, including Medi-Span and First DataBank, on or around January 2016.

49. Upon information and belief, on or around January 2016, a listing for the B-DONNA product appeared on the FDA website, DailyMed, with a marketing start date of December 30, 2015.

50. Copies of the B-DONNA labels and package inserts are also available on the DailyMed website.

51. Upon information and belief, listings for Defendants' B-DONNA oral tablets also appeared in Medi-Span and First DataBank on or around January 2016. A copy of the Medi-Span listing is attached as Exhibit C.

52. Medi-Span and First DataBank (collectively, the "Drug Databases") are subscription-based drug information and interactions compendia used nationwide by health care professionals, payers and pharmaceutical manufacturers and others to evaluate medications that are currently on the market.

53. The Drug Databases are also used to determine whether generic substitutes are available for brand name products.

54. Upon information and belief, pharmaceutical products that are labeled as pharmaceutically equivalent are "linked" to one another in the Drug Databases.

55. Pharmaceutical equivalence means that the products contain the same active ingredients, in the same amounts, and in the same dosage forms.

56. According to their labels and package inserts, the B-DONNA products contain the same active ingredients, in the same amount, and in the same dosage form as DONNATAL.

57. Upon information and belief, the labels and package inserts for the B-DONNA oral tablets have been copied from the labels and package inserts for DONNATAL, including the "Indications and Usage" section, which claims that the product has been reviewed and classified by FDA.

58. Upon information and belief, the labels and package inserts for the B-DONNA oral tablets contain numerous false or misleading representations, including that the product has been reviewed or classified by FDA.

59. The B-DONNA labels and package inserts for the B-DONNA products also claim that the B-DONNA product is available in an elixir form. However, upon information and belief, no such product has been launched.

60. Upon information and belief, based upon the representations on the products' labels and package inserts, the B-DONNA products have become "linked" to DONNATAL in the Drug Databases.

61. The "linking" of products within the Drug Databases is used by pharmacies, pharmacists, wholesalers, pharmaceutical buyers, and insurance companies and others to determine whether there are any generic alternatives available for a particular brand product.

62. Based upon this linkage in the Drug Databases, these relevant market players believe that the linked pharmaceutical products are generic equivalents and therefore substitutable for the brand name product.

63. Upon information and belief, these relevant market players, including wholesalers, distributors, pharmacies, pharmacists and others, are being deceived into believing that the B-DONNA products are FDA-approved generic equivalents that may be substituted for DONNATAL.

64. Notwithstanding Defendants' advertising and promotion efforts, B-DONNA products are not generic equivalents to or substitutes for DONNATAL.

65. In addition, by listing the B-DONNA products on Medi-Span after September 19, 2011, when the FDA unequivocally made approval for new

products entering the market mandatory, Defendants are misleading consumers that their products have been approved by the FDA.

66. In order to be listed in the Drug Databases, an applicant must normally submit an FDA Approval Letter and the corresponding approval number.

67. The FDA would not have provided an Approval Letter or approval number to Defendants because the Defendants do not have an approved NDA or ANDA for their drug products, nor were they participants in the FDA's DESI review process for PBA products.

68. Defendants' listings of their B-DONNA products with the Drug Databases and DailyMed have been made available to Plaintiff customers in this District and have adversely impacted Plaintiff's sales of their DONNATAL products in this District.

69. Upon information and belief, Defendants' copying of Plaintiff's drug labels and product inserts was not done as part of a submission to the FDA or other government agency, nor was it permitted or contemplated under any legislative provision authored by Congress.

70. The false and misleading information on the B-DONNA drug labels and product inserts and the listings of the B-DONNA products with the Drug

Databases and FDA through its DailyMed website have been transmitted to customers throughout the United States.

71. Plaintiff will suffer an immediate and further substantial loss in market share as a direct result of the unauthorized entry of B-DONNA onto the market and Defendants' false and misleading representations regarding the B-DONNA product.

72. Upon information and belief, wholesalers and pharmacies have or will reduce inventories of DONNATAL as a result of the launch of the B-DONNA products.

73. Upon information and belief, believing B-DONNA to be a generic alternative for DONNATAL, pharmacists are or will automatically substitute B-DONNA when he or she receives a prescription for DONNATAL.

74. As a result, patients will be exposed to a drug that has not been safety-approved by the FDA. Besides the threat to public health, adverse effects may be attributed to DONNATAL because patients are often unaware of the substitution, thus resulting in the erosion of Plaintiff's goodwill.

75. Defendants' promotion, marketing and listing of the B-DONNA products as a generic alternative to and substitutable for DONNATAL products is

both false and misleading and it has caused irreparable injury to Plaintiff and will continue to both damage Plaintiff and to deceive and potentially harm the public unless enjoined by this Court.

76. Plaintiff has been and will be harmed by Defendants' false and misleading representations. Defendants' efforts have and will continue to mislead consumers into believing that B-DONNA is an FDA-approved "generic" that may be automatically substituted for DONNATAL.

77. Defendants' efforts have harmed and will continue to harm Plaintiff's unique brand, as purchasers of PBA pharmaceuticals have come to recognize Plaintiff as the only entity currently allowed to market PBA pharmaceuticals.

78. Upon information and belief, Defendants are aware or should reasonably be aware of the contractual relationships that Plaintiff maintain with pharmaceutical manufacturers, distributors and/or suppliers in order to make and sell DONNATAL, and the economic benefits to Plaintiff that flow from these relationships.

79. Upon information and belief, Defendant Pressman directed, sanctioned, actively participated in, and voluntarily and intentionally caused the above-mentioned unlawful conduct by the corporate Defendants.

COUNT I

FALSE ADVERTISING IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

80. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

81. Defendants' representations that B-DONNA pharmaceuticals are FDA-approved PBA products substitutable for DONNATAL pharmaceuticals are false or misleading representations of fact.

82. Upon information and belief, the labels and package inserts for the B-DONNA oral tablets contain numerous false or misleading representations, including that the product has been reviewed or classified by FDA.

83. Defendants' statements have actually deceived or have the tendency to deceive a substantial segment of their audience.

84. Defendants' false and misleading claims about the B-DONNA products are material and likely to influence the purchasing decisions of health care professionals and patients who consume Plaintiff's products.

85. Defendants' false or misleading representations were and are made in interstate commerce.

86. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and is continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits, which Plaintiff would have made but for the false and deceptive representations by Defendants.

87. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

COUNT II

TRADEMARK INFRINGEMENT IN VIOLATION OF LANHAM ACT SECTION 32 (15 U.S.C. § 1114)

88. Plaintiff repeats and re-alleges each and every allegation contained in the proceeding paragraphs of this Complaint, and incorporate them herein by reference.

89. The B-DONNA mark is a colorable imitation of Plaintiff's federally-registered DONNATAL mark and Defendants' unauthorized use of the B-DONNA mark in commerce in connection with the sale, offering for sale, distribution, and/or advertisement of its competing pharmaceutical products is likely to cause confusion, cause mistake, and/or deceive prospective or actual customers and other members of the public.

90. Upon information and belief, Defendants' purpose in using the B-DONNA mark was and is to deceive, mislead and confuse customers, so as to trade on the substantial reputation and goodwill enjoyed by Plaintiff in connection with the DONNATAL mark.

91. Defendants' adoption and unauthorized use of the B-DONNA mark infringes Plaintiff's exclusive rights in its federally registered DONNATAL mark in violation of Section 32, 15 U.S.C. § 1114, of the Lanham Act.

92. Defendants' acts of infringement as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Plaintiff's business, reputation, and goodwill, unless Defendants' unlawful conduct is enjoined by this Court.

93. Plaintiff is entitled to recover all damages sustained by Defendants' actions, all profits realized by Defendants through their infringing use of the DONNATAL mark, and the costs of this action.

94. Defendants' actions have been willful and deliberate, entitling Plaintiff to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Plaintiff is entitled to an award of reasonable attorneys' fees.

COUNT III

UNFAIR COMPETITION IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

95. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

96. The DONNATAL mark is a highly distinctive mark as an indicator of source that is uniquely associated with Plaintiff as the provider of the only FDA-approved PBA pharmaceuticals.

97. Defendants' unauthorized use of the B-DONNA mark in commerce is likely to cause confusion, cause mistake, and/or deceive prospective or actual customers and other members of the public as to the source, origin, sponsorship or approval of Defendants' products and/or its affiliation, connection, or association with Plaintiff.

98. Upon information and belief, Defendants' purpose in using the B-DONNA mark was and is to deceive, mislead and confuse customers as to the source or origin of Defendants' goods and/or their affiliation with Plaintiff, so as to

trade on the substantial reputation and goodwill enjoyed by Plaintiff in connection with the DONNATAL mark.

99. Defendants' unauthorized use of the B-DONNA mark in commerce constitutes unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

100. Defendants' acts of infringement as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Plaintiff's business, reputation, and goodwill, unless Defendants' unlawful conduct is enjoined by this Court.

101. Plaintiff is entitled to recover all damages sustained by Defendants' actions, all profits realized by Defendants through their infringing use of the B-DONNA mark, and the costs of this action.

102. Defendants' actions have been willful and deliberate, entitling Plaintiff to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Plaintiff is entitled to an award of reasonable attorneys' fees.

COUNT IV

VIOLATIONS OF THE GEORGIA UNIFORM DECEPTIVE PRACTICES ACT

103. Plaintiff repeats and re-alleges each and every allegation contained in the proceeding paragraphs of this Complaint, and incorporates them herein by reference. .

104. O.C.G.A. § 10-1-372 provides that:

> (a) A person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, he:
>
> > (1) passes off goods or services as those of another;
> >
> > (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> > (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;
> > ...
> > (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;
> > ...
> > (7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> > ...
> > (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

105. O.C.G.A. § 10-1-373 provides a private right of action to enforce the provisions of O.C.G.A. § 10-1-372.

106. In the course of their business, Defendants, by and through their infringing use of the B-DONNA mark and their false and misleading representations of fact and conduct concerning the B-DONNA products, have engaged in and continue to engage in deceptive trade practices in violation of O.C.G.A. § 10-1-372.

107. Defendants have willfully engaged in these actions, knowing them to be deceptive.

108. By reason of Defendants' conduct, Plaintiff has suffered and will continue to suffer damage to its business, reputation and goodwill.

109. Pursuant to O.C.G.A. § 10-1-373, Plaintiff is entitled to enjoin Defendants' unlawful conduct as well as recover reasonable attorneys' fees.

110. Defendants, by virtue of their B-DONNA database listings, misrepresent that their pharmaceuticals are approved by the FDA and are legally marketed in violation of Va. Code § 59.1-200(2).

111. As a proximate result of Defendants' misrepresentations, Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause

immediate and irreparable harm, for which Plaintiff is entitled to injunctive relief and damages in an amount to be proven at trial.

COUNT V

COMMON LAW UNJUST ENRICHMENT

112. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

113. Defendants' unauthorized use and copying of Plaintiff's DONNATAL labels; listing of the unauthorized B-DONNA product with the Drug Databases and FDA – and attendant misrepresentations that their B-DONNA product is a generic equivalent and substitutable for Plaintiff's DONNATAL; and the manufacture and sale of the B-DONNA product without license or authorization of Plaintiff are benefits conferred on and inequitably retained by Defendants.

114. Defendants knew of the above-listed benefits because these benefits were the result of Defendants' unauthorized and illegitimate actions.

115. These benefits were valuable to Defendants and Defendants should have reasonably expected to repay Plaintiff for these benefits, for at least the

reason that any such benefits would have only been conferred on Defendants through a bargained-for license agreement from Plaintiff.

116. Defendants accepted or retained these benefits without paying Plaintiff for their value.

117. Defendants' receipt of the benefits without compensation to Plaintiff would be unjust.

COUNT VI

TORTIOUS INTERFERENCE WITH CONTRACT OR BUSINESS RELATIONSHIPS

118. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

119. Defendants are aware of Plaintiff's valid contractual and business relationships with manufacturers, distributors and/or suppliers that are maintained in order to make and sell DONNATAL.

120. Defendants are aware of the economic benefits that flow to Plaintiff as a result of these contractual relationships. Defendants are further aware of the

probability that economic benefits would continue to flow to Plaintiff in the future as a result of these contractual relationships.

121. Defendants' wrongful and intentional conduct as set forth in this Complaint has interfered with Plaintiff's valid contractual relationships.

122. Upon information and belief, Defendants' wrongful and intentional conduct has caused third parties to discontinue or fail to enter into anticipated relationships with Plaintiff.

123. Defendants' conduct has proximately caused damage to Plaintiff in the form of lost sales and prescriptions, and has thereby caused the diminution and erosion of the current and future economic benefits that flow from Plaintiff valid contractual relationships.

There is a reasonable certainty that absent Defendants' intentional conduct, Plaintiff would have realized the full economic benefits of their contractual relationships.

JURY DEMAND

Plaintiff demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court enter judgment in their favor and grant the following relief:

A. Compensatory damages, consisting of general and special damages, in an amount to be proven at trial;

B. An award of punitive damages;

C. A preliminary and permanent injunction enjoining Defendants, and all others acting in privity (IS THIS WORD SPELLED CORRECTLY?) or in concert with them, from listing, marketing, offering for sale, or selling "B-DONNA" or any other unauthorized PBA pharmaceuticals;

D. Cancellation of U.S. Reg. No. 4,883,086 pursuant to 15 U.S.C. § 1119;

E. Reasonable attorney fees and costs in prosecuting this action as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and Georgia law; and

F. Award Plaintiff such other relief as the interests of justice may require.

DATE: January 6, 2016

Respectfully submitted,

CONCORDIA PHARMACEUTICALS INC., S.À.R.L.

BY: /s/ W. Brian Holladay
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